MAR - 2 2001

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K002468

1. Submitter's Identification:

SAN UP s.a.
Ruta 8 #2967 (1650) San Martin
Buenos Aires, Argentina 1650

Contact: Mr. Jorge Shemi
President

Date Summary Prepared: August 1, 2000

2. Name of the Device:

SAN UP s.a. Nebulizer Compressor Model 3050

3. Predicate Device Information:

DeVilbiss Model 5650 (Pulmo-Aide) Compressor Nebulizer, K#923888

4. Device Description:

This line-powered piston compressor is housed in a rectangular white plastic cabinet (case) with a sliding lid. Dimensions are 125mmx 263mm x 90mm and weighs 1.720 kg. It consists of a motor-driven piston compressor and a switch; it contains no microprocessors or other electronic components. It operates from 115 VAC, 60 Hz. It is supplied with tubing, a nebulizer chamber, and two face masks.

Models 3050 and 3040 are identical in specification, working and size, except Model 3040 is an infant version which is colorful, and, which "play stickers" can be placed on.

In use, the compressor is placed on a flat surface and the cover is opened to reveal an outlet hose barb to which the oxygen (air) delivery tubing and nebulizer are connected. Inlet air to the compressor passes through a replaceable filter.

5. Intended Use:

This nebulizer compressor is an AC-powered air compressor intended to provide a source of compressed air for medical purposes for use in home health care. This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma, allergies, etc.

6. Comparison to Predicate Devices:

The subject and predicate devices are AC-powered, contain the same filter material, meet Environmental, Safety and EMC requirements, and are in the similar compressor operating pressure and liter flow ranges. Performance characteristics are basically the same. All are fairly lightweight.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following Environmental and Safety Testing was conducted::

a. Maximum pressure and flow under all combinations of the following:
   - Temperatures of $+5^0$ and $+20^0$C, and 40^0C with 90% RH
   - Line voltage of 95, 115, and 132 V
b. Storage at -20^0C and at $+60^0$C
c. Fluid soil resistance
d. Surface and air temperatures
e. Sinusoidal vibration
f. Impact (drop) resistance
g. Leakage current and dielectric withstand (electrical safety)

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It is our conclusion that the SAN UP s.a. Nebulizer Compressor, with Disposable Nebulizer, Model 3050, device sample(s) tested met all relevant requirements of the aforementioned test.

In addition, the following EMC testing was conducted by CITECH:

a. Radiated and Conducted Emission per CISPR 11
b. Magnetic Field Emission per MIL-STD-462D, Method RE101
c. Fast surges per Reviewer Guidance document

Because the compressor contains no electronic components (e.g., microprocessors), the radiated and conducted immunity tests were not applicable. The device was tested as described in CITECH Test Report #490-391c to simulate, as closely as possible, actual operating conditions.

The device tested met the EMC criteria recommended by the FDA.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

We have demonstrated that the SAN UP s.a. Nebulizer Compressor Model 3050 is as safe and effective as predicate devices presently on the market, based on electrical, mechanical, environmental and EMC testing results outlined in the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions". We also adhered to FDA's DCRND "Reviewer Guidance for Home Use Respiratory Devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2001

Ms. Susan D. Goldstein-Falk
San Up s.a.
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

Re: K002468
Nebulizer Compressor, Model 3050
Regulatory Class: II (two)
Product Code: 73 BTI
Dated: November 30, 2000
Received: December 4, 2000

Dear Ms.Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

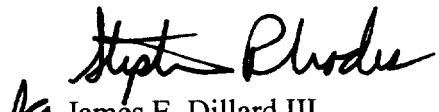
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit A

510(k) Number (if known): K002468

Device Name: SAN UP s.a. Nebulizer Compressor, Model 3050

Indications For Use:

This nebulizer compressor is an AC-powered air compressor intended to provide a source of compressed air for medical purposes for use in home health care. This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma, allergies, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002468

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)